

crispprd 1.0



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## Abstract

**Grant Number:** 5R01MH061695-02

**PI Name:** KANOUSE, DAVID E.

**PI Title:** SENIOR BEHAVIORAL SCIENTIST

**Project Title:** A TRAINING INTERVENTION TO ENHANCE ADHERENCE TO HAART

**Abstract:** *Adherence to highly active antiretroviral therapy (HAART) is vital to successful treatment, including prevention of drug resistance and loss of therapeutic options. Several studies are currently evaluating programs that use a psycho-educational approach to enhance adherence. The proposed study will be the first to examine whether such an intervention is more effective when combined with a practice trial of an inert medication regimen that mimics HAART. The intervention will "hit hard and early" by intervening with patients before they begin treatment to help them get the best start possible and to minimize development of patterns of non-adherence that may be difficult to alter. A sample of 270 patients from 5 university-affiliated HIV outpatient clinics in California who are either initiating or restarting (after a hiatus of at least 6 months) HAART will be randomized into one of 3 conditions: (1) an adherence training intervention with psycho-educational components alone; (2) the same psycho-educational intervention delivered in the context of a brief training trial of an inert medication that mimics HAART; or (3) usual care. The primary outcome will be adherence, which will be assessed using electronic monitoring and self-report at baseline and 1, 3, 6 and 12 months after patients begin HAART. Viral load will be measured at the same time points, together with resistance assays, to assess clinical outcomes at one year. The additive effect of implementing the practice trial will be assessed by comparing adherence at 1 month following initiation of HAART in the two intervention arms, and both intervention arms will be compared with the usual care control. Adherence subsequent to 1 month, viral load, and drug resistance will be important secondary outcomes. Longitudinal analyses will be conducted to characterize the lagged effects of adherence on clinical outcomes. Study data will be used*

*to calibrate a structural model of this relationship that could then be used to predict viral load and CD4 trajectory for patients before treatment onset under various adherence assumptions. If proven effective, the training intervention could assist practitioners in preparing their patients to adhere well and gain optimal benefit from HAART.*

***Thesaurus Terms:***

*AIDS therapy, antiAIDS agent, behavior modification, health behavior, longitudinal human study, patient care management, therapy compliance*

*Retroviridae, antiviral agent, belief, counseling, culture, drug resistance, health education, neuropsychology, outcomes research, patient monitoring device, social psychology, viremia*

*behavioral /social science research tag, clinical research, human subject, interview, questionnaire*

**Institution:** RAND CORPORATION  
BOX 2138, 1700 MAIN ST  
SANTA MONICA, CA 90407

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